REMARKS/ARGUMENTS

Claims 29-32 and 34-47 are pending. Claims 12-13, 16-17, 24-28 and 33 are canceled by way of this amendment. Claims 30-32, 38-40 are amended. Claims 41-47 are new. Support for claim amendments and new claims may be found in claims 29-32, 39, and in the specification at pages 8, 32-33, 36, and the Examples.

No new matter is added by these amendments. Following amendments, 18 total claims are pending, including 3 independent claims.

I. Claims 12, 13 and 28 are rejected under 35 USC 102(b) as being anticipated by Horwitz, US Patent No. 5,108,745 (the '745 patent).

Applicants respectfully disagree for the reasons previously of record. However, solely in an effort to advance prosecution, and reserving the right to re-present these claims in a continuing application, Applicants have canceled claims 12, 13 and 28 (and the claims depending therefrom).

In view thereof, the Examiner is respectfully requested to withdraw this ground as rejection as moot in view of the cancellation of claims 12, 13 and 28.

II. Claims 9, 10, 12, 13, 16, 17, 24-27, and 29-37 have been rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The Examiner alleges that the specification provides vaccine examples of only whole BCG, ESAT6, Rv2031c, and Rv0569, and two fragments of Rv2031c. It is further alleged that the specification does not teach any vaccines comprising the other sequences in the listing of SEQ ID NOs: 1-45.

Claims 9, 10, 12, 13, 16, 17, 24-27, and 33 are canceled by way of these amendments, rendering their rejection moot. Applicants respectfully traverse the rejection of claims 29-32 and 34-37.

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the

> same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.[1]
>
> There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976).[2]
>
> The test for written description is whether "the description clearly allow[s] persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). An applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).[3]
>
> For some biomolecules, examples of identifying characteristics include a sequence . . . As explained by the Federal Circuit, "(1) examples are not necessary to support the adequacy of a written description . . ."[4]

Independent claim 29 (from which all other pending claims depend) reads as follows:

> A therapeutic vaccine against tuberculosis comprising one or more mycobacteria polypeptides and a pharmaceutically acceptable polymeric carrier bound to the one or more polypeptides or a pharmaceutically acceptable adjuvant, which polypeptides are upregulated or expressed during the latent stage of the mycobacteria infection which is characterized by low-oxygen tension in the microenvironment of the mycobacteria, wherein the one or more polypeptides has an amino acid sequence selected from SEQ ID NO 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, and 45.

Despite the Examiner's contention, support for vaccines comprising one or more polypeptides of SEQ ID NOs 1-45 is found, *e.g.*, in Table 1, beginning at page 9 of the

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1 35 U.S.C. 112, first paragraph.

2 MPEP §2163 I.A.

3 MPEP §2163.02.

4 MPEP §2163 II.A.3.(a).

specification, and at pages 8 and pages 32-33. Thus, one of skill in the art would understand, with "reasonable clarity", that the Applicants were in possession of the invention that is now claimed. The specification clearly allows persons of ordinary skill in the art to recognize that the Applicants invented what is claimed, complete with each and every sequence recited in the claims.

The Examiner appears to rely in part on the "vaccine examples" beginning at page 55 of the specification as limiting of what the Applicants have described elsewhere in the specification. As noted at page 55, "[i]t will be understood that the following examples are illustrative of the present invention and are not a limitation thereof." Further, "examples are not necessary to support the adequacy of a written description".[5]

In view of the above, the Examiner is respectfully requested to reconsider and withdraw this ground of rejection.

III. *Claims 9, 10, 12, 16, 17, 24-27, 30-33, and 39-40 are rejected under 35 USC 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.*

Applicants respectfully disagree as to all rejections. However, in view of the cancellation of claims 9, 10, 12, 16, 17, 24-27, and 33, the rejections as to these claims are moot. Applicants reserve the right to represent these claims in a continuing application.

Claim 30 is rejected under 35 USC 112, second paragraph, as allegedly indefinite. It is allegedly unclear how more than one sequence listed in claim 29 may have SEQ ID NO:24.

While disagreeing that the claim lacks clarity, solely in an effort to advance prosecution, Applicants have amended claim 30 to recite that "*one of said* one or more polypeptides has an amino acid sequence of SEQ ID NO:24."

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5 *Id.*

Claims 31 and 39 are rejected under 35 USC 112, second paragraph, as allegedly indefinite. The relationship of the polypeptide and the antigen fusion partner is allegedly unclear.

While disagreeing that the claims lack clarity, solely in an effort to advance prosecution, Applicants have amended the claims to specify that the "antigen expressed by bacteria within the mycobacteria family" is "*heterologous* to said one or more polypeptides." The amendment is believed to address the alleged lack of clarity, and is supported at page 47 of the specification, *i.e.*,

> "[t]he fusion partner can, in order to enhance immunogenicity, be another polypeptide derived from *M. tuberculosis*, such as . . ."

Applicants have added dependent claims 41-44, which are directed to specific aspects where the fusion partner is either a different polypeptide of SEQ ID NO: 1-45 or is an antigen expressed by bacteria within the mycobacteria family that is different from SEQ ID NO: 1-45.

Claims 32 and 40 are rejected as under 35 USC 112, second paragraph, as allegedly indefinite. It is allegedly that the claims contain improper Markush grouping.

Applicants have amended claims 32 and 40 to reflect "and" between the final two members of the closed group.

Claim 38 is rejected under 35 USC 112, second paragraph, as allegedly indefinite in recitation of both 'peptides' and 'polypeptides'.

While disagreeing that the claim lacks clarity, solely in an effort to advance prosecution, Applicants have amended the claim to recite "polypeptides" in all instances. Support for the use of this term for amino acid chains of any length may be found in the specification at page 38.

In view of the above remarks and the amendments in the claims, the Examiner is respectfully requested to reconsider and withdraw all rejections and permit the application to proceed to issuance.

Please charge any deficiency in any fee, or credit any overpayment, to deposit account number 08-3040.

Respectfully Submitted,

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